IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (JLH) [redacted]
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	

NS RESPONSES TO CONCISE STATEMENT OF FACTS IN SUPPORT OF SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S MOTIONS FOR SUMMARY JUDGMENT

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Dated: January 12, 2024

[redacted]

TABLE OF CONTENTS

[redacted]

TABLE OF ABBREVIATIONS

Abbreviation	Description
'851 Patent	U.S. Patent No. 9,994,851
'590 Patent	U.S. Patent No. 10,227,590
'827 Patent	U.S. Patent No. 10,266,827
'851 Pat. PH Excerpt	Excerpts of the prosecution history for U.S. Patent No. 9,994,851
'590 Pat. PH Excerpt	Excerpts of the prosecution history for U.S. Patent No. 10,227,590
'827 Pat. PH Excerpt	Excerpts of the prosecution history for U.S. Patent No. 10,266,827
'150 Appl. PH Excerpt	Excerpts of the prosecution history for U.S. Patent Application No. 13/741,150
0644 CERI Rpt.	"The assessment of exon skipping activities by PMO in myotube using Endo-Porter DMSO as a transfection reagent," May 2023, Chemicals Evaluation and Research Institute, Japan (CERI), Study Number 936-21-M-0644
0661 CERI Rpt.	"The assessment of exon skipping activities by PMO in myotube using Endo-Porter DMSO as a transfection reagent," May 2023, Chemicals Evaluation and Research Institute, Japan (CERI), Study Number 936-21-M-0661
ASO	Antisense oligonucleotide
Clemens 2020	Clemens et al., "Safety Tolerability, and Efficacy of Viltolarsen in Boys With Duchenne Muscular Dystrophy Amenable to Exon 53 Skipping," JAMA Neurology (2020):E1-E10
Dowdy Op. Rpt.	Opening Expert Report of Steven F. Dowdy, Ph.D., dated September 7, 2023
Esau Reb. Rpt.	Rebuttal Expert Report of Christine C. Esau, Ph.D Regarding Non-Infringement of the UWA Patents, dated October 11, 2023
Esau Tr.	Transcript of Christine Esau Deposition held November 3, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
Ex. ____	Exhibit ____[1]
Fletcher Tr.	Transcript of Sue Fletcher Deposition held September 27, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)

[1] Refers to Exhibits to the accompanying Declaration of Megan E. Dellinger in Support of Sarepta Therapeutics, Inc. and The University of Western Australia's Motions for Summary Judgment and Motions to Exclude Certain Opinions and Testimony of Plaintiff/Counter-Defendants' Experts.

[redacted]

Abbreviation	Description
Kamholz Op. Rpt.	Expert Report of Scott E. Kamholz, Esq., dated September 8, 2023
Gendron Tr.	Transcript of Gardner Gendron Deposition held July 11, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
Hastings Op. Rpt.	Expert Report of Dr. Michelle L. Hastings Regarding Invalidity of the UWA Patents, dated September 8, 2023
Hastings Tr.	Transcript of Michelle Hastings, Ph.D. Deposition held November 17, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
Hosfield Op. Rpt.	Expert Report and Disclosure of Mark J. Hosfield, dated September 8, 2023
Hosfield Tr.	Transcript of Mark Hosfield Deposition held November 1, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
Kamholz Reply Rpt.	Reply Expert Report of Scott E. Kamholz, Esq., dated October 27, 2023
Kamholz Tr.	Transcript of Scott E. Kamholz Esq. Deposition held November 3, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
NS	Plaintiff/Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.
NS Final Non-Infringement Contentions	Nippon Shinyaku Co. Ltd. and NS Pharma, Inc.'s Noninfringement Contentions, served July 11, 2023
NS Japan	Plaintiff/Counter-Defendant Nippon Shinyaku Co., Ltd.
NS Pharma	Counter-Defendant NS Pharma, Inc.
NS Response to ROG 35	Nippon Shinyaku Co. Ltd. and NS Pharma, Inc.'s First Supplemental Responses and Objections to Sarepta Therapeutics, Inc.'s Interrogatory No. 35, served August 15, 2023
PTO	United States Patent and Trademark Office
Sarepta	Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc.
Takeda 2021	Takeda et al., "Exon-Skipping in Duchenne Muscular Dystrophy," J. Neuromuscl. Dis. (2021) 8:S343-S358
Toda Tr.	Transcript of Masaya Toda Deposition held June 28-29, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
UWA	Counter-Plaintiff The University of Western Australia
Viltepso® Label	Viltepso® (viltolarsen) Prescribing Information (Revised: 3/2021)

[redacted]

Abbreviation	Description
Watanabe Tr.	Transcript of Naoki Watanabe Deposition held June 26-27, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
Wilton Patents	U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827
Wilton Product Patents	U.S. Patent Nos. 9,994,851; 10,227,590
Wilton Tr.	Transcript of Steve Wilton Deposition held June 15, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)

[redacted]

I. *STATEMENT OF FACTS IN SUPPORT OF MOTION #1*: SUMMARY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NOS. 9,994,851 AND 10,227,590

A. Structure of Viltepso® (Viltolarsen) and the Wilton Product Patents: U.S. Patent Nos. 9,994,851 ("the '851 Patent") and 10,227,590 ("the '590 Patent")

RESPONSE TO 1.1: Admitted.

RESPONSE TO 1.2: Denied as stated. Viltepso® is a pharmaceutical product that contains viltolarsen as an ingredient. Ex. 44 [Viltepso® Label], § 11 ("VILTEPSO is supplied in single-dose vials containing 250 mg/5 mL viltolarsen (50 mg/mL) in 0.9% sodium chloride. Each milliliter of VILTEPSO contains 50 mg viltolarsen and 9 mg sodium chloride in water for injection.").

RESPONSE TO 1.3: Admitted.

RESPONSE TO 1.4: Denied as stated. Viltepso® is a pharmaceutical product that contains viltolarsen as an ingredient. Ex. 44 [Viltepso® Label], § 11 ("VILTEPSO is supplied in single-dose vials containing 250 mg/5 mL viltolarsen (50 mg/mL) in 0.9% sodium chloride. Each milliliter of VILTEPSO contains 50 mg viltolarsen and 9 mg sodium chloride in water for injection.").

RESPONSE TO 1.5: Admitted.[2]

RESPONSE TO 1.6: Denied as stated. Viltepso® is a pharmaceutical product that contains viltolarsen as an ingredient. Ex. 44 [Viltepso® Label], § 11 ("VILTEPSO is supplied in single-dose vials containing 250 mg/5 mL viltolarsen (50 mg/mL) in 0.9% sodium chloride. Each milliliter of VILTEPSO contains 50 mg viltolarsen and 9 mg sodium chloride in water for injection.").

RESPONSE TO 1.7: Admitted.

[2] NS has admitted this fact in view of the Court's claim construction but reserves the right to challenge claim construction on appeal.

[redacted]

RESPONSE TO 1.8: Admitted.[3]

RESPONSE TO 1.9: Admitted.[4]

RESPONSE TO 1.10: Denied as stated. Viltepso® is a pharmaceutical product that contains viltolarsen as an ingredient. Ex. 44 [Viltepso® Label], § 11 ("VILTEPSO is supplied in single-dose vials containing 250 mg/5 mL viltolarsen (50 mg/mL) in 0.9% sodium chloride. Each milliliter of VILTEPSO contains 50 mg viltolarsen and 9 mg sodium chloride in water for injection."). Further, the base sequence of viltolarsen is "CCTCCGGTTC TGAAGGTGTT C," and does not contain at least 12 consecutive bases of SEQ ID NO: 195. Ex. 44 [Viltepso® Label], § 11 (listing the base sequence of viltolarsen as "CCTCCGGTTC TGAAGGTGTT C").

RESPONSE TO 1.11: Admitted.

RESPONSE TO 1.12: Admitted.

RESPONSE TO 1.13: Admitted.[5]

RESPONSE TO 1.14: Denied as stated. Viltepso® is a pharmaceutical product that contains viltolarsen as an ingredient. Ex. 44 [Viltepso® Label], § 11 ("VILTEPSO is supplied in single-dose vials containing 250 mg/5 mL viltolarsen (50 mg/mL) in 0.9% sodium chloride. Each milliliter of VILTEPSO contains 50 mg viltolarsen and 9 mg sodium chloride in water for injection.").

RESPONSE TO 1.15: Admitted.

RESPONSE TO 1.16: Admitted.

[3] *See supra* text accompanying n.2.

[4] *See supra* text accompanying n.2.

[5] *See supra* text accompanying n.2.

[redacted]

B. Nippon Shinyaku Co., Ltd. ("NS Japan") and NS Pharma, Inc. ("NS Pharma") (collectively, "NS") Have Sold Viltepso® in the United States

RESPONSE TO 1.17: Admitted.

RESPONSE TO 1.18: Admitted.

C. Expert Testimony Addressing Whether Viltepso® Meets the Limitations of the Wilton Product Patents

RESPONSE TO 1.19: NS admits that "Dr. Steven Dowdy has opined that NS's Viltepso® meets every limitation of the claims of the Wilton Product Patents." However, NS denies that "Viltepso® meets every limitation of the claims of the Wilton Product Patents" because the base sequence of viltolarsen does not include at least 12 consecutive bases of SEQ ID NO: 195. Ex. 44 [Viltepso® Label], § 11 (listing the base sequence of viltolarsen as "CCTCCGGTTC TGAAGGTGTT C"); Ex. 21 [Esau Reb. Rpt.], ¶¶23-48, 63-64.

RESPONSE TO 1.20: Admitted as stated. However, for clarity, NS further states that Dr. Esau contends that NS does not indirectly infringe the Wilton Product Patents due to a lack of knowledge that the use of Viltepso® would infringe the Wilton Product Patents. Ex. 21 [Esau Reb. Rpt.], ¶¶23-48, 63-64.

RESPONSE TO 1.21: Admitted as stated. However, for clarity, NS further states that Dr. Esau contends that NS does not indirectly infringe the Wilton Product Patents due to a lack of knowledge that the use of Viltepso® would infringe the Wilton Product Patents. Ex. 21 [Esau Reb. Rpt.], ¶¶23-48, 63-64.

RESPONSE TO 1.22: Admitted.

RESPONSE TO 1.23: Admitted.

RESPONSE TO 1.24: Admitted as stated. However, for clarity, NS further states that Dr. Esau contends that NS does not indirectly infringe the Wilton Product Patents due to a lack of knowledge that the use of Viltepso® would infringe the Wilton Product Patents. Ex. 21 [Esau

[redacted]

Reb. Rpt.], ¶¶23-48, 63-64.

RESPONSE TO 1.25: Admitted.

RESPONSE TO 1.26: Denied as stated. Dr. Hastings conducted an invalidity analysis of the Wilton Patents utilizing Sarepta's interpretation of the Wilton Product Patents, in the event that the Court adopted Sarepta's interpretation. *See* Ex. 22 [Hastings Op. Rpt.]. The approach of providing alternative theories—including "arguments analyzed under an opposing party's interpretation of the claims"—has been expressly permitted by this Court. *Intel Corp. v. Future Link Sys., LLC*, 268 F. Supp. 3d 605, 614 (D. Del. 2017) ("Future Link's concerns that Intel's infringement position is inconsistent with its licensing defense, and further, that Intel's experts only analyzed commercialization under Future Link's interpretation of the claims, do not entitle it to summary judgment. As the Court previously noted … such alterative arguments, and arguments analyzed under an opposing party's interpretation of the claims, are permissible."). However, NS admits that Dr. Hastings has acknowledged that Viltepso® meets every limitation of claim 1 of the '851 Patent, including the limitation "wherein the base sequence comprises at least 12 consecutive bases of [SEQ ID NO: 195]" under Sarepta's interpretation of the Wilton Patents.

RESPONSE TO 1.27: Denied as stated. Dr. Hastings conducted an invalidity analysis of the Wilton Patents utilizing Sarepta's interpretation of the Wilton Product Patents, in the event that the Court adopted Sarepta's interpretation. *See* Ex. 22 [Hastings Op. Rpt.]. The approach of providing alternative theories—including "arguments analyzed under an opposing party's interpretation of the claims"—has been expressly permitted by this Court. *Intel Corp. v. Future Link Sys., LLC*, 268 F. Supp. 3d 605, 614 (D. Del. 2017) ("Future Link's concerns that Intel's infringement position is inconsistent with its licensing defense, and further, that Intel's experts

[redacted]

only analyzed commercialization under Future Link's interpretation of the claims, do not entitle it to summary judgment. As the Court previously noted … such alterative arguments, and arguments analyzed under an opposing party's interpretation of the claims, are permissible."). However, NS admits that according to Dr. Hastings, the ASOs designed by Dr. Hastings having only thymine bases and no uracil bases meet the limitation "wherein the base sequence comprises at least 12 consecutive bases of [SEQ ID NO: 195]" under Sarepta's interpretation of the Wilton Patents.

RESPONSE TO 1.28: Admitted.

D. NS's Final Non-Infringement Contentions and Pleadings

RESPONSE TO 1.29: Admitted as stated. However, for clarity, NS further states that NS's Final Non-Infringement Contentions contend that NS does not indirectly infringe the Wilton Product Patents due to a lack of knowledge that the use of Viltepso® would infringe the Wilton Product Patents. NS Ex. 58 [NS Final Non-Infringement Contentions], 11-12.

RESPONSE TO 1.30: Admitted as stated. However, for clarity, NS further states that NS's Answer to Counter-Plaintiffs' Amended Counterclaims contend that NS does not indirectly infringe the Wilton Product Patents due to a lack of knowledge that the use of Viltepso® would infringe the Wilton Product Patents. D.I. 344 at 17-18, 20-21.

[redacted]

II. *STATEMENT OF FACTS IN SUPPORT OF MOTION #2*: SUMMARY JUDGMENT OF NO LOST PROFITS

A. Plaintiff NS Japan and Non-Party NS Pharma Are Distinct Corporate Entities

RESPONSE TO 2.1: Admitted.

RESPONSE TO 2.2: Admitted.

B. [redacted].

RESPONSE TO 2.3: Admitted.

RESPONSE TO 2.4: Denied as stated. Nippon Shinyaku is [redacted]. Ex. 53, NS00036893 at 94 (Art. 2), 98-99 (Arts. 14-17). Admitted that [redacted]

C. [redacted]

RESPONSE TO 2.5: Admitted that NS Pharma has [redacted] Denied insofar as Sarepta implies that Nippon Shinyaku does not [redacted] For example, [redacted] Ex. 53, NS00036893 at 94 (Arts. 2-3), 98-99 (Arts. 14-17).

RESPONSE TO 2.6: Admitted.

RESPONSE TO 2.7: Admitted that Nippon Shinyaku's [redacted] Denied

[redacted]

insofar as Sarepta implies this is the only [redacted]. Nippon Shinyaku [redacted] Ex. 53, NS00036893 at 97-98 (Art. 13).

D. [redacted]

RESPONSE TO 2.8: Admitted [redacted]. Denied to the extent Sarepta implies that the [redacted]. *Id.* at 97 (Art. 13.3, 13.4, 13.5, 13.6). And [redacted] *Id.* at 06.

RESPONSE TO 2.9: Admitted.

RESPONSE TO 2.10: The first sentence is admitted. The second sentence is denied as stated. [redacted] Ex. 53, NS00036893 at 97. [redacted] NS00036893 at 06-07 (implementing [redacted]); Ex. 56, NS00036968 (implementing [redacted]); Ex. 54, NS00091311 (same for 2022); Ex. 57, NS00091312 (implementing [redacted]

[redacted]

[redacted]

[redacted]); *see also* NS Ex. 55, Gendron Dep. at 110:18-112:13 (explaining that "[redacted]

[redacted]

[redacted]

[redacted]); Ex. 49, Hosfield Op. Rpt. at 23-26 (detailing [redacted]).

RESPONSE TO 2.11: Admitted.

RESPONSE TO 2.12: Admitted that, as of service of expert reports in this case, [redacted]

[redacted]

[redacted]

[redacted]

[redacted] Ex. 53, NS00036893 at 06-07 (implementing [redacted]

[redacted]); Ex. 56, NS00036968 (implementing [redacted]

[redacted]); Ex. 54, NS00091311 (same for [redacted]; Ex. 57, NS00091312 (implementing [redacted]

[redacted]); *see also* NS Ex. 55, Gendron Dep. at 110:18-112:13 (explaining that [redacted]

[redacted]

[redacted]

[redacted]"); Ex. 49, Hosfield Op. Rpt. at 23-26 (detailing [redacted]).

[redacted]

E. [redacted]

RESPONSE TO 2.13: Admitted that Mr. Hosfield's analysis relies [redacted] Denied insofar as Sarepta implies Mr. Hosfield did not also base his analysis on other information, such as witness testimony, financial information, and [redacted]. NS Ex. 54, Hosfield Rpt. at 23-26, 61-79.

RESPONSE TO 2.14: Admitted that the quoted language is from a translation of an internal Nippon Shinyaku document. Denied to the extent Sarepta characterizes "[redacted] Exs. 51 & 52, NS00065827 at 27. The paragraph Sarepta selectively quotes states in full:

[redacted]

Id. (emphasis added). Thus, the document merely mentions "[redacted]" Notably, Sarepta declined to question Nippon Shinyaku's corporate representative regarding the selectively-quoted statement. NS Ex. 56, Toda Dep. at 58:11-63:20.

RESPONSE TO 2.15: Admitted.

[redacted]

RESPONSE TO 2.16: Admitted.

RESPONSE TO 2.17: Denied as stated. [redacted] Ex. 53, NS00036893 at 06-07 (implementing [redacted]); Ex. 56, NS00036968 (implementing [redacted]); Ex. 54, NS00091311 (same for 2022); Ex. 57, NS00091312 (implementing [redacted]; *see also* NS Ex. 55, Gendron Dep. at 110:18-112:13 (explaining that [redacted]"); Ex. 49, Hosfield Op. Rpt. at 23-26 (detailing [redacted]). Sarepta declined to ask Nippon Shinyaku's and NS Pharma's Rule 30(b)(6) designees about [redacted] *See* NS Ex. 56, Toda Dep. at 63:21-77:11 (discussing [redacted]); NS Ex. 55, Gendron Dep. at 110:3-112:19 (discussing [redacted]. As of today, [redacted]. NS Ex. 59, Gendron Decl. ¶¶ 2-3.

[redacted]

III. *STATEMENT OF FACTS IN SUPPORT OF MOTION #3*: SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT AND NO *WALKER PROCESS* FRAUD

RESPONSE TO 3.1: NS admits that PCT/AU2005/000943 was filed on June 28, 2005. However, as Sarepta stated in its Response to Interrogatory No. 14, PCT/AU2005/000943 "claims priority to Australian Application No. 2004903474 filed June 28, 2004. Thus, the Asserted Sarepta Claims are entitled to a priority date of at least June 28, 2005, the filing date of PCT2005/000943." *See* NS Ex. 27, Sarepta's Supplemental Responses and Objections to NS's Interrogatories (Nos. 1-6, 8-23, 25-30, 32-324), dated August 15, 2023, at 60.

RESPONSE TO 3.2: Ex. 17, Bates number SRPT-VYDS-0134063-65 appear to be inventor declarations directed to U.S. patent application no. 13/741,150 signed by Stephen Donald Wilton and Sue Fletcher on March 26, 2013. The '150 Application claims priority through three continuation applications to the 2005 PCT Application as well as to AU 204903474. Ex. 17, SRPT-VYDS-0130221-225.

RESPONSE TO 3.3: NS admits the '172 Application was filed on September 14, 2017 by Amy E. Mandragouras, listing The University of Western Australia as the applicant. Ex. 14, SRPT-VYDS-0002996-997.

RESPONSE TO 3.4: NS admits the '172 Application claimed priority to U.S. patent application no. 14/740,097, filed on January 14, 2013, which claims priority to the '150 Application, filed on June 24, 2011, claims priority through three continuation applications to the 2005 PCT Application as well as to AU 204903474. Ex. 14, SRPT-VYDS-0002993-94.

RESPONSE TO 3.5: NS admits that the inventorship declarations signed on March 26, 2013 and submitted for the '150 Application were also submitted for the '172 Application.

RESPONSE TO 3.6: NS admits that the Harding paper is listed in an Information Disclosure Statement dated September 22, 2017, along with over 1160 other non-patent literature,

[redacted]

foreign patent documents, U.S. patents and patent application publications and office action responses. SRPT-VYDS0003124-187.

RESPONSE TO 3.7: NS admits that the Examiner purported to have considered each of the approximately 1170 references submitted in the September 22, 2017 Information Disclosure Statement on October 1, 2017. Ex. 14, SRPT-VYDS-0004616-771.

RESPONSE TO 3.8: NS states the '172 Application issued as the '851 patent on June 12, 2018. Ex. 14, SRPT-VYDS-0002984.

RESPONSE TO 3.9: NS admits that Ex. 14, SRPT-VYDS-0004929-34 reflects that Marsha Rose Gillentine transmitted a Power of Attorney on March 28, 2018 for the '172 Application and a Notice of Acceptance of Power of Attorney was mailed on April 2, 2018 to Sterne, Kessler, Goldstein & Fox P.L.L.C.

RESPONSE TO 3.10: NS admits that Sterne, Kessler, Goldstein & Fox P.L.L.C. is listed as the attorney, agent, or firm on the '590 and '827 patents.

RESPONSE TO 3.11: NS admits that the application issuing as the '590 patent was filed on August 24, 2018.

RESPONSE TO 3.12: NS admits that the application issuing as the '827 patent was filed on August 24, 2018.

RESPONSE TO 3.13: NS admits that the Harding paper was listed in an Information Disclosure Statement dated November 20, 2018, along with over 1,050 other non-patent literature references, foreign patents and U.S. patents and patent application publications, that was submitted to the PTO during prosecution of the application that issued as the '590 patent. SRPT-VYDS-0005451-608.

[redacted]

RESPONSE TO 3.14: NS admits the Examiner purportedly considered each of the references submitted in the November 20, 2018 Information Disclosure Statement on December 20, 2018. SRPT-VYDS-0005626-737.

RESPONSE TO 3.15: NS admits that the Harding paper was listed in an Information Disclosure Statement dated January 17, 2019, along with over 1,050 other non-patent literature references, foreign patents and U.S. patents and patent application publications, that was submitted to the PTO during prosecution of the application that issued as the '827 patent. SRPT-VYDS-0006280-465.

RESPONSE TO 3,16: NS admits the Examiner purportedly considered each of the references submitted in the January 17, 2019 Information Disclosure Statement on February 4, 2019. SRPT-VYDS-0006478-589.

RESPONSE TO 3.17: NS admits that the phrase "knew or should have known" appears in the cited paragraphs of Dr. Kamholz's expert reports.

RESPONSE TO 3.18: NS admits that this accurately characterizes the cited passages from Dr. Kamholz's deposition testimony and opening expert report.

RESPONSE TO 3.19: NS admits that this accurately characterizes the cited passages from Dr. Kamholz's deposition testimony. It is Dr. Kamholz's opinion that Dr. Wilton, Dr. Fletcher, and Ms. Mandragouras "knew or should have known" [redacted] because [redacted]

[redacted]

[redacted]"

Ex. 24, Kamholz Opening ¶ 32.

RESPONSE TO 3.20: NS admits that Dr. Kamholz's expert reports state that Stephen Wilton, Sue Fletcher, and Amy Mandragouras "know or should have known" [redacted] for the reasons provided in the cited paragraphs.

RESPONSE TO 3.21: NS admits that this accurately characterizes the cited passages from Dr. Kamholz's deposition testimony. It is Dr. Kamholz's opinion that Ms. Mandragouras "knew or should have known [redacted]" Ex. 24, Kamholz Opening ¶ 79.

RESPONSE TO 3.22: NS admits that in the cited passage from Dr. Wilton's deposition testimony, [redacted] NS Ex. 39, Fletcher Dep. 77:16-78:4, 81:11-18, 84:16-85:9 [redacted]); NS Ex. 38, Wilton Dep. 145:15-146:3.

RESPONSE TO 3.23: NS admits that this accurately characterizes Dr. Fletcher's deposition testimony from the cited passage. However, [redacted].

[redacted]

RESPONSE TO 3.24: NS admits that this accurately characterizes Dr. Fletcher's deposition testimony from the cited passage. [redacted]

[redacted]

Dated: January 12, 2024

Respectfully submitted,

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[redacted]

CERTIFICATE OF SERVICE

I, Amy Dudash, certify that on January 12, 2024, I caused a copy of NS'S RESPONSES TO CONCISE STATEMENT OF FACTS IN SUPPORT OF SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S MOTIONS FOR SUMMARY JUDGMENT, which was filed under seal, to be served via electronic mail on the following counsel of record:

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